K062416

Section 5

NOV 17 2006

510(k) Summary
Retinal Functional Imager (RFI)

Date: October 10, 2006

Submitter's Name:

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Contact Person:

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Trade Name:

Retinal Functional Imager (RFI)

Classification Name:

Camera, Ophthalmic, AC Powered

Classification:

Classification	Primary	Secondary
Product Code:	HKI	HLI
Class:	II	II
Regulation Number	21 CFR 886.1120	21 CFR 886.1570
Regulation Name	Ophthalmic Camera	Ophthalmoscope

Substantial Equivalence:

The Retinal Functional Imager (RFI) is considered to be substantially equivalent to its predicate devices:

- Kowa Fundus Camera FX-500 – cleared under K954780;
- Zeiss FF450 VISUPAC – cleared under K011877;
- Canon – Ophthalmoscope Laser Blood Flow Meter – LBFM Model 100 – cleared under K992606; and
- Heidelberg Ophthalmoscope Retina Flow Meter – cleared under K943955

without raising new safety and/or effectiveness issues.

All these devices are ophthalmic imaging management systems intended to capture, display, and store images of the retina to aid in diagnosing or monitoring diseases of the retina that may be observed and photographed.

Device Description:

The **Retinal Functional Imager (RFI)** is a mydriatic fundus imaging camera intended for taking red-free images. The RFI is comprised of the following subassys:

- An optical system for illuminating and imaging the retina. The optical imaging includes a stroboscopic light source for sequential rapid imaging of the retina.
- A high resolution CCD camera.
- An electronic unit for driving the light source.
- A software package for operating the system, controlling the illumination, grabbing the images, data browsing and data analysis.

The device is also capable of using 35 mm film or using a digital camera similar to the predicate devices. Visible light is used for observation. Alignment and focusing is manual via the fundus camera controls.

Under red-free imaging, the Retinal Functional Imager (RFI) provides, through a series of multiple flashes, the ability to observe and register the blood flow velocity and path of motion.

Intended Use

The Retinal Functional Imager (RFI) is intended to observe, capture, display, and store images of patients' fundus (retina) under mydriatic conditions with the information of blood flow (velocity) and path of flow in a retinal vessel, to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.

The Retinal Functional Imager Technology

The Retinal Functional Imager (RFI) is a mydriatic fundus camera designed to take retinal images using a standard high resolution digital camera mounted on a conventional fundus camera and a stroboscopic light source. The images can be taken at high frame rates. To facilitate this imaging frame rate, the flash illumination system of the fundus camera has been modified to permit the delivery of strobe flashes at the camera's full frame rate in a fixed train of discharges. This extension of normal fundus camera capabilities allows new information to be obtained from the retina by extracting reflectance changes due to the motion of red blood cells through the blood circulation of the retina between images. The software is able to map the blood flow through blood vessels in the eye and determine the velocity of the flow by tracking the motion of the blood cells, taking into account various control factors.

The fundus camera has a manufacturer-rated magnification specification different for each available magnification setting. The digital camera demagnification power and sensor size give a calibration of digital camera pixels to actual microns on the retina and is used in the determination of blood flow velocity.

RFI Software - The software for the RFI is comprised of a Grab and Browse module. The Grab module is responsible for acquiring and saving raw image data to a disk. The Browse module provides a user interface for entering patient data and selecting the mode in which Grab will operate; it also allows the operator to review the acquired data before continuing with data grab operations. Additional embedded software provides the Grab module with hardware state control and monitoring services.

Performance Testing

Acceptance criteria for compliance with the standards are detailed in Optical Imaging's IEC 60601-1 Technical Report, the Risk Analysis for the RFI device, and the verification and validation reports.

Non-clinical validation is detailed in Optical Imaging's System Verification and Validation Reports. Validation was performed on the device to establish its effectiveness and performance. The device was found to perform as well as equivalent devices on the market. Blood flow velocity measurements showed that flow velocity measurements obtained were within the design specifications of the system, were repeatable and accurate with reference to known velocity simulated data images, and that subject data measurements were both reasonable and consistent.

The main system risks addressed are electromagnetic compatibility, system electrical safety, optical radiation level and mechanical stability. These were evaluated as part of Optical Imaging's electrical safety test and verification activities.

The main software risks addressed are communication loss, power loss and out of limit conditions. These were evaluated as part of Optical Imaging's Software Test Procedure for validation of the software.

The User Interface risks addressed are functional clarity, patient data integrity and security and possible user misuse. These were also evaluated as part of Optical Imaging's Software Test Procedure for validation of the software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2006

Optical Imaging Ltd.
c/o Jonathan Kahan
Hogan & Hartson, LLP
555 Thirteenth Street, NW
Washington, DC 20004

Re: K062416
Trade/Device Name: Retinal Functional Imager (RFI)
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI; HLI
Dated: October 25, 2006
Received: October 25, 2006

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

INDICATIONS FOR USE

510(k) Number (if known): K062416

Device Name: Retinal Functional Imager (RFI)

Indications for Use: The Retinal Functional Imager (RFI) is intended to observe, capture, display, and store images of patients' fundus (retina) under mydriatic conditions with the information of blood flow (velocity) and path of flow in a retinal vessel, to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.

Prescription Use ___X___ (21 C.F.R. § 801.109 subpart D) OR Over the Counter Use_____ (21 C.F.R. § 801 subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

11/15/2006

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K062416